

National Specified List of Susceptible Products

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Carmen A. Catizone, MS, RPh, DPh Executive Director/Secretary On February 20, 2004, the National Association of Boards of Pharmacy[®] (NABP[®]) released the updated Model Rules for the Licensure of Wholesale Distributors. The updated Model Rules, part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, were provided to assist state boards of pharmacy in maintaining the integrity of the United States medication distribution system through the regulation of wholesale distributors. The updated Model Rules are the result of a concerted effort between NABP and other representatives from pharmacy, government, and the wholesale distributor industry to protect the public from the ill effects of counterfeit drugs and devices.

In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "Specified List of Susceptible Products." In attempts to reduce redundancy and confusion as states update and adopt regulation, it is highly suggested that states adopt the National Specified List of Susceptible Products that will be developed in conjunction with Food and Drug Administration (FDA), NABP, and other invited industry stake holders. By mid 2004, NABP will appoint a standing committee, the Drug Advisory Coalition. The Drug Advisory Coalition will be primarily responsible for revising the National Specified List of Susceptible Products on no less than an annual basis. The Drug Advisory Coalition will also be charged initially with drafting criteria that detail standards and guidance for the revision process.

The following page contains the drugs currently included in the National Specified List of Susceptible Products. This List, which was adapted from the Florida Statewide Pharmaceutical Services and Drug Wholesaler Advisory Council (Florida Department of Health), represents a starting point for states that have an imminent need for such direction. NABP is currently considering other additions to the List, but anticipates that the Drug Advisory Coalition will revise the List by late 2004.

National Specified List of Susceptible Products

The National Association of Boards of Pharmacy Model Rules for the Licensure of Wholesale Distributors defines the "Specified List of Susceptible Products" as a specific list of drugs or devices to be designated by the state, or a third party approved by the state, determined to be susceptible to adulteration, counterfeiting, or diversion and posing the potential for a greater public health risk.

- Combivir[®] (lamivudine/zidovudine)
 Crixivan[®] (indinavir)
 Diflucan[®] (fluconazole)

- 4. Epivir[®] (lamivudine)
 5. Epogen[®] (epoetin alfa)
- 6. Gamimune® (globulin, immune)
- 7. Gammagard[®] (globulin, immune)
- 8. Immune globulin
- 9. Lamisil® (terbinafine) 10. Lipitor® (atorvastatin) 11. Lupron® (leuprolide)
- 12. Neupogen® (filgrastim)
- 13. Nutropin AQ[®] (somatropin, E-coli derived)
 14. Panglobulin (globulin, immune)
- 15. Procrit[®] (epoetin alfa)
- 16. Retrovir[®] (zidovudine)
 17. Risperdal[®] (risperidone)
- 18. Rocephin[®] (ceftriaxone)
- 19. Serostim[®] (somatropin, mannalian derived)
- 20. Sustiva® (efavirenz)
- 21. Trizivir® (abaçavir/lamivudine/zidovudine)
- 22. Venoglobulin® (globulin, immune)
- 23. Videx[®] (didanosine)
- 24. Viracept[®] (nelfinavir) 25. Viramune[®] (nevirapine)
- 26. Zerit® (stavudine)
- 27. Ziagen® (abacavir) 28. Zocor® (simvastatin)

- 29. Zofran[®] (ondansetron) 30. Zoladex[®] (goserelin) 31. Zyprexa[®] (olanzapine)